# 510(K) SUMMARY

(as required by 21 CFR 807.92)

NOV - 9 2011

A. 510K Number : K110276

B. Applicant

Company Name: Hanuri Distribution, Inc
Adress: 9601 Owensmouth Ave. # 8 Chatsworth, CA 91311 USA
Contact Person: Jung H Moon
Phone: 818-998-1023, Fax: 818-998-0277

C. Proprietary and Established Names: Same as B

D. Regulatory Information

1. Proprietary/Trade Name: Powerpress Unit
2. Classification Name: Compressible Limb Sleeve
3. Classification Panel : Cardiovascular
4. Common / Usual Name: Sequential Compression Device
5. Classification / Product Code: Class II / JOW 870.5800

E. Intended Use

The Powerpress Unit Sequential Circulator is a manual, sequential, pneumatic compression device, intended for the primary or adjunctive treatment of primary or secondary lymphedema. The device is also intended for the additional or alternate treatment of venous insufficiency, and chronic venous stasis ulcers associated with venous insufficiency, as well as general treatment of swelling of the extremities. The device is intended for home or hospital use.

F. Predicate Device

Powerpress Unit is substantially equivalent to the following

| Predicate Device | Manufacturer | 510(k)# |
|---|---|---|
| SC-3008 Sequential Circulator | Bio Compression System, Inc | K043423 |

G. Device Description

Powerpress Unit is a sequential pneumatic compression device designed to apply compression to a limb. The device is composed of two components.

- Pneumatic Manual Pump
- Limb Sleeve or garment composes of 4 chambers

Powerpress Unit enables different treatment pressure (30 ~ 100mmHg). Treatment pressure and time should be used according to physician prescription. When activated, air flows into chamber, the pump provides gradient pressurization to the chambers (sequential inflation of distal to proximal, with distal chambers inflated to a greater pressure than the proximal ones).

After each chamber is inflated, the pressure is held constant until all chambers are inflated, in order to prevent reverse gradient flow. Once all chambers are inflated, they are then all released simultaneously, and the cycle repeats. Pressure within chambers are adjustable – pressure to chamber 1 is controlled by user-adjusted regulator on the pump. Pressure in chamber 2, 3 & 4 are individually lowered according to the default factory setting.

Gradient: appx 7%, example: Foot 60mmHg – Ankle 56mmHg – Calf 52mmHg - Thigh 48mmHg
Cycle Time: Inflation 36 sec / Deflation 24 sec
Inflation time each chamber : 1st chamber(foot) – 36 sec, 2nd chamber(ankle) – 27 sec, 3rd chamber – 18 sec, 4th chamber(thigh) – 9 sec

A calibrated dial gauge displays pressure in the range of 0 ~ 160 mmHg

H. Technological Characteristics
The manufacturer believes that the technological characteristic of the Powerpress Unit is substantially similar to those of the predicate devices.

Powerpress Unit has very similar components to its predicate devices and very similar principles of operation.

I. Performance Standards
Bench testing and side by side comparisons were done with predicate devices to assure equivalence in performance. No new safety and/or effectiveness issues are raised.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Hanuri Distribution, Inc.
% Mr. Jung Hyun Moon
9601 Owensmouth Avenue #8
Chatsworth, California 91311

NOV - 9 2011

Re: K110276
Trade/Device Name: Powerpress Unit Sequential Circulator
Regulation Number: 21 CFR 870.5800
Regulation Name: Compressible Limb Sleeve
Regulatory Class: II
Product Code: JOW, IRP
Dated: October 20, 2011
Received: October 21, 2011

Dear Mr. Moon:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin L Keith

for Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K110276

PJ 1 of 1

# Indication for Use Statement

510(k) Number (if known) : K110276

Device Name : Powerpress Unit

Indication For Use :

The Powerpress Unit Sequential Circulator is a manual, sequential, pneumatic compression device, intended for the primary or adjunctive treatment of primary or secondary lymphedema. The device is also intended for the additional or alternate treatment of venous insufficiency, and chronic venous stasis ulcers associated with venous insufficiency, as well as general treatment of swelling of the extremities. The device is intended for home or hospital use.

Prescription Use **X** And/Or Over-The Counter Use _____

(Part21 CFR801 Subpart D)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

---

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K110276